Allied Rehabilitation Using Web-Based Caregiver MEDiated Exercises for STROKE: The ARMED4STROKE Trial Design

Corien D. M. Nikamp, Gert Kwakkel, Erik C. Prinsen, Rinske H. M. Nijland, Marijn Mulder, Erwin E. H. van Wegen, Hermie J. Hermens, and Jaap H. Buurke

Abstract This paper describes the design of the Armed4Stroke program. Patients after stroke and their caregivers are included as a couple. The caregiver is trained as a co-therapist by a physiotherapist experienced in providing caregiver-mediated exercises (CME) to support and motivate the patient. The program consists of 8 weeks of gait and gait-related exercises, complementary to regular rehabilitation therapy. The couple will receive a tailor-made exercise program, which is adapted to the patients' abilities and goals and is progressive in nature. The program is supported by videos with exercise instructions, which are accessible using a web-based tele-rehabilitation system. It is hypothesized that CME, supported with tele-rehabilitation is able to promote daily mobility and to reduce anxiety and depression in patients after stroke and their caregivers.

C. D. M. Nikamp (✉) · E. C. Prinsen · H. J. Hermens · J. H. Buurke
Roessingh Research and Development, Enschede, The Netherlands
e-mail: c.nikamp@rrd.nl

University of Twente, Enschede, The Netherlands

G. Kwakkel · R. H. M. Nijland · M. Mulder
Amsterdam Rehabilitation Research Centre, Reade, Amsterdam, The Netherlands

G. Kwakkel · M. Mulder
Department of Rehabilitation Medicine, Amsterdam Neuroscience and Amsterdam Movement Sciences, Amsterdam UMC, VUmc, Amsterdam, The Netherlands

E. E. H. van Wegen
Department of Rehabilitation Medicine, Amsterdam Movement Sciences, Amsterdam UMC, VUmc Amsterdam, Amsterdam, The Netherlands

© The Author(s), under exclusive license to Springer Nature Switzerland AG 2022

D. Torricelli et al. (eds.), *Converging Clinical and Engineering Research on Neurorehabilitation IV*, Biosystems & Biorobotics 28,
https://doi.org/10.1007/978-3-030-70316-5_68

1 Introduction

Recovery of walking ability is an important goal for patients post stroke. Stroke rehabilitation is typically front loaded, with resources mainly focused on inpatient care, where professionals support patients in their exercises. After inpatient treatment, support often tapers off and the majority of stroke survivors become physically inactive, whereas poor activity levels correlate with physical and psychological outcomes and quality of life. Consequently, stroke survivors and their caregivers experience the transition from inpatient care to the community as a significant hurdle.

Two key elements can be used to augment the level of exercise, even after inpatient care is finished: (1) Caregiver Mediated Exercise (CME); and (2) extension of rehabilitation to the patients' own home. CME is an approach in which caregivers are actively involved in the rehabilitation program after stroke. During CME, the patient performs exercises with an informal caregiver, under supervision of a trained physiotherapist. The couple will receive an exercise program adapted to patients' abilities and goals. A proof-of-concept trial showed that CME, combined with e-Health technology was feasible, safe and effective in reducing anxiety of patients and depression of caregivers [1]. The patient and caregiver may experience a smoother transition to the home situation and the involvement of the caregiver did not increase caregiving burden [2]. Hence, CME is a promising paradigm to improve outcomes on psychological measures. In addition, the caregiver could support and motivate the patient to continuing exercises at home, when professional support from inpatient rehabilitation tapers off. (2) The caregiver is instructed and trained as a "co-therapist" to maintain their support in the home situation. To support the couple, there are regular face-to-face sessions in which the exercise program will be adapted according to the progress of the patient and to (adjusted) abilities and goals. The program is supported by videos of the exercise, which are built in a web based tele-rehabilitation system. The combination of face-to-face supported CME with tele-rehabilitation aims to promote self-generated physical activity and to increase motivation. The CME and tele-rehabilitation components are included in the Allied Rehabilitation using caregiver MEDiated exercises for Stroke (Armed4Stroke) program, which already starts during the subacute phase post stroke. Compared to the previous proof-of-concept trial, there is an increased focus on rehabilitation in the home situation and the number of videos in the online tele-rehabilitation system suitable for performance at home is substantially increased.

This paper describes the design of the trial that aims to assess the added value of the Armed4Stroke program: (1) to improve the level of daily mobility at home; (2) on length of inpatient stay, activities of daily living and psychosocial measures.

2 Material and Methods

2.1 Study Design

The study has a single, observer-blinded randomized controlled trial design. Patients are randomly allocated to either 8 weeks of Armed4Stroke program in addition to usual inpatient or outpatient care (i.e. experimental group), or to 8 weeks of usual care alone (i.e. control group). The study is registered in the Dutch trial register as NL7422 and approved by the Medical Ethics Review Committee of the VU University Medical Centre, Amsterdam, The Netherlands.

2.2 Participants

Seventy-two stroke patients and their caregiver are recruited in multiple centers in the Netherlands, during their inpatient and/or outpatient stay. The caregiver can be any person close to the patient (like partner, family member or neighbor). Inclusion criteria for the patient are: <3 months after stroke; ≥18 years of age; written informed consent; able to understand the Dutch language; knowing and able to appoint a caregiver who wants to participate in the program (with a max. of 2 caregivers); living independently before the stroke; living at home or planned to be discharged home; being able to follow instructions; sufficiently motivated for CME. Inclusion criteria for the caregiver are: ≥18 years of age; written informed consent; able to understand the Dutch language; sufficiently motivated for CME; medically stable and physically able to perform the exercises together with the patient. Serious comorbidity that interferes with participation is exclusion criterion for both patient and caregiver.

2.3 Study Procedure

Prior to the study, all involved physiotherapists received training in applying the Armed4Stroke program. The measurements are performed by a trained assessor who is blinded to treatment allocation. Adverse and serious adverse events are monitored.

2.4 Intervention

The Armed4Stroke program consists of 8 weeks of complementary exercise therapy done with a caregiver, supported by tele-rehabilitation, next to the usual therapy. The goals and progress of the patient are leading in setting the complementary exercise therapy. The tailor-made program contains task-specific exercises focusing on gait

and gait related activities and is progressive in nature from basic (transfer) activities to high level gait exercises. The program is supported by videos of exercises, which are accessible using the web-based tele-rehabilitation system. The couple is asked to do exercises minimally 5 times per week for 30 min. During inpatient stay, couples are advised to perform the exercises during the weekend, when patients are mostly inactive. During the 8-week program, at least 4 face-to-face sessions with the physical therapist are planned to adapt the exercise program according to the progress of the patient. Participants in the control group will receive usual care according to the clinical guidelines of the Royal Dutch Society of Physical Therapy [3].

2.5 Outcome Measures

Outcome measures are assessed at baseline (T0), following the 8-week intervention or control period (T1), and 6 months after randomization (T2). The primary outcome is the self-reported mobility domain of the Stroke Impact Scale 3.0. This is a disease-specific questionnaire that evaluates self-reported health status in eight domains [4]. Secondary outcomes for patients are: walking ability (10m walking speed and 6 min walking distance), balance (Berg Balance Scale) and lower limb strength (Motricity Index), assessed using clinical tests. In addition, the amount of daily activity during one week is measured using MOX-activity sensors, and length of inpatient stay are recorded in participating rehabilitation settings for included stroke patients. Furthermore, scales like Rivermead Mobility Index and Nottingham Extended ADL, assessing self-reported mobility, activity of daily living, and functional outcome are used. Caregiving strain is assessed in caregivers. Patients and caregivers are assessed on quality of life, self-efficacy, family functioning, fatigue, anxiety and depression and the preparedness for the transition from in/outpatient setting to the home.

2.6 Data Analysis

Baseline values will be calculated and between-group differences will be studied to determine whether groups are comparable at baseline using the appropriate statistical tests. The primary and secondary outcomes will be compared between the intervention and control group at the different time points (T0, T1, T2) using multilevel regression analysis.

3 Results

Currently, 8 subjects (4 M/4 F, age 54–78 years, 35–91 days after stroke) are included in the study that started in two rehabilitation centers. The first subjects are about to start T2 assessment. Additional rehabilitation centers are joining the study to further increase inclusion rates.

4 Discussion

The current trial is an extension of the previously conducted proof-of-concept trial that showed that CME combined with tele-rehabilitation was feasible and safe, and effective in improving psychological outcomes [1]. Since the amount of exercises available in the tele-rehabilitation system is extended, the current trial also aims to improve outcomes on a functional level.

5 Conclusion

Results of the trial are expected to confirm that CME, supported with tele-rehabilitation are able to promote daily mobility and activities of daily living, decrease length of inpatient stay, and to reduce anxiety and depression in patients after stroke and reduce caregivers' burden.

Acknowledgments This study was funded by the ZonMW/Wetenschappelijk College Fysiotherapie (WCF), grant nr 858001102. We would like to thank E. Kret for contributing to performing the study measurements.

References

1. J. Vloothuis, M. Mulder, R. Nijland, Q. Goedhart, M. Konijnenbelt, H. Mulder et al., Caregiver-mediated exercises with e-health support for early supported discharge after stroke (CARE4STROKE): a randomized controlled trial. PloS One **14**(4), e0214241 (2019)
2. J. Vloothuis, M. Depla, C. Hertogh, G. Kwakkel, E. van Wegen, Experiences of patients with stroke and their caregivers with caregiver-mediated excercises during the CARE4STROKE trial. Disabil Rehabil **42**(5), 698–704 (2020)
3. J. Veerbeek, E. van Wegen, R. van Peppen, P. van der Wees, E. Hendriks, M. Rietberg et al., What is the evidence for physical therapy poststroke? A systematic review and meta-analysis. PloS One **9**(2), e87987 (2014)
4. P. Duncan, R. Bode, S. Min Lai, S. Perera, Rasch analysis of a new stroke-specific outcome scale: the stroke impact scale. Arch. Phys. Med. Rehabil. **84**(7), 950–963 (2003)